

AMERICAN DAIRY PRODUCTS INSTITUTE

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December 2, 2004

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Docket No. 2004D-0453

To Whom It May Concern:

The American Dairy Products Institute (ADPI) is the national trade association of the leading manufacturers of processed dairy products, including dry and evaporated milks, whey and modified whey products, lactose, and cheese. Accordingly, ADPI members are keenly interested in regulatory developments that potentially affect the safety of processed dairy products, such as the proposed changes to the Food and Drug Administration's Compliance Policy Guide under the Federal Import Milk Act (FIMA).

ADPI fully supports the underlying purposes of FIMA, which is intended to ensure that imported dairy products are manufactured and processed under safe and sanitary conditions. The permit process is the mechanism by which FDA polices imports of dairy products. ADPI is concerned that, by broadening the number of products that may be imported without permits, the agency may be opening the door to potentially unsafe products, as well as potentially subjecting importers to a lesser regulatory standard than that imposed on domestic manufacturers.

Specifically, ADPI believes that sour cream, cultured milk, acidified milk, and yogurt should continue to be covered by the permit requirement, as set forth in the Compliance Policy Guide. These products are classified as Grade "A" dairy products under the Pasteurized Milk Ordinance (PMO) and, as such, must meet certain rigorous safety and quality standards. We are concerned that relaxation of the permit process for these products could result in the importation of inferior, and potentially less safe processed dairy products.

Similarly, we do not support the potential waiver of permit requirements for products packaged in hermetically sealed containers. Again, the requirement to obtain a permit under FIMA provides the agency with a pivotal opportunity to ensure that dairy products imported into the United States meet this country's strict safety and quality standards. We do not believe that it is in the interest of

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our industry or American consumers to allow more products to enter the country without strict regulatory oversight.

We appreciate the opportunity to provide our comments on the proposed changes to the Compliance Policy Guide. We stand ready to answer any questions that the agency may have on this, or related issues concerning processed dairy products.

Respectfully submitted,

James J. Page

Dan Meyer Chief Executive Officer

Director of Technical Services